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## Electronic Mail Message

**Sensitivity:** COMPANY CONFIDENTIAL

**Date:** 29-Mar-2000 12:06pm  
**From:** Kendrick, Juliette  
jskl@cdc.gov

**Dept:**  
**Tel No:**

**TO:** 'SFP15REG Account' ( SFP15REG@A1 )

**Subject:** Re: Participation in FDA Public Meeting to be Held 3/30/00 - Revised Agenda

Rose, attached are my slides for the presentation. They are in Freelance. Hope this is OK for your needs. If not, I can arrange to send you something else when I return to the office on Friday.

See you tomorrow.

Juliette K

<<FDASUPPA.PRE>>

> -----Original Message-----

> From: SFP15REG Account [SMTP:SFP15REG@cder.fda.gov]  
> Sent: Monday, March 27, 2000 3:39 PM  
> To: SFP15REG Account; wsoller; jdel@cdc.gov; mmcguffin@ahpa.org;  
> annette@crnusa.org; dmattison@modimes.org; jbrinckmann@tradmed.com;  
> frid@interchange.ubc.ca; swolfe@citizen.org; pannys@dhmh.state.md.us;  
> amitchell@slone.bu.edu; jskl@cdc.gov; gpoakley@mindspring.com  
> Subject: Participation in FDA Public Meeting to be Held 3/30/00 -  
> Revised Agenda  
> Sensitivity: Confidential

> You are confirmed to participate in the Food and Drug Administration's  
> (FDA) public meeting on safety issues associated with dietary use during  
> pregnancy. The meeting will be held in the Crystal Ballroom of the  
> Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, Maryland, on  
> Thursday, March 30, from 9:00 a.m. to 5:00 p.m.

> There have been a couple of changes in the order of presentation. The  
> revised agenda is attached for your information.

> Please be sure to provide me with an electronic version of your  
> presentation prior to or on the day of the meeting. Your presentations  
> will become part of the public docket.

> If you have any questions, I can be reached by email at  
> sfpl5reg@cder.fda.gov or telephone at 301-594-5468 (this is my direct  
> line, so please leave a message.)

> I look forward to meeting you on March 30.

> Rose Cunningham

> Project Manager << File: C:\MYDOCU~1\STRFUN~1\AGND.DOC >> << File:  
> C:\MYDOCU~1\STRFUN~1\FPANEL.DOC >>



# Dietary Supplement Use During Pregnancy: Maternal Health Effects

Presentation to the FDA  
March 30, 2000

Juliette S. Kendrick MD  
Division of Reproductive Health  
Centers for Disease Control  
and Prevention

## Background Statistics

- US 1996: 6.2 million pregnancies
  - **62% live births**
  - **22% induced abortions**
  - **16% miscarriage**
- Any exposure during pregnancy may affect large number of women and infants
- Medication use in US studies (Rx and OTC):
  - **44-92% used at least one drug during pregnancy**
    - ▶ **average 3 to 5.5 medications per woman among users**
  - **no US data on dietary supplement use**

## Nausea and Vomiting ("Morning Sickness")

- 60-80% of pregnant women
- Most severe in first trimester
- Wide range of severity
  - Mild inconvenience
  - Moderate incapacitation
  - Severe hospitalization
    - ▶ 1-2% of pregnant women hospitalized
- Unexplained associations:
  - severity better pregnancy outcome
  - severity when fetus is female

| —  
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# Edema

- 75% of pregnant women
- Can progress through a range of severity:
  - mild ankle swelling
  - edema plus hypertension (may be asymptomatic)
  - pre-eclampsia (26/1000 deliveries)
  - eclampsia (life threatening) (0.56/1000 deliveries)
- Delay in seeking care may result in more severe disease and maternal complications, including death.

## References: Popular Materials

1. E. Eisenberg. *What to Expect When You're Expecting*. NY 1991.
2. P. Ody. *Herbs for a Healthy Pregnancy*. IL 1999.
3. A. Roman. *The Natural Pregnancy Book: Herbs, Nutrition, and Other Holistic Choices*. CA 1997.
4. N. Wesson. *Natural Mothering*. VT 1997.

## What Do the Books Recommend?

- "Treat medicinal herbs as you would any drugs during pregnancy. Do not take them except on the advice of your doctor." <sup>1</sup>
- "Herbs can play a part in this vision by helping to ease the minor ills of pregnancy, to soothe the pains of childbirth, and to set baby on the road to a contented and well-balanced life."
- "It is particularly rewarding to be able to recommend medical herbalism for treatment of recurrent miscarriages." "Taking the whole plant or plant part is a far safer method of using its healing properties than that employed by modern pharmaceuticals."



## Selected Conditions for Which Treatment During Pregnancy with Herbal Remedies is Recommended<sup>2,3,4</sup>

- Abdominal pain
- Anemia
- Backache
- Bladder and kidney problems
- Fainting
- Fatigue
- Sinusitis
- Teeth and gum problems
- High blood pressure
- Threatened miscarriage
- Skin conditions
- Insomnia

## How Are Dietary Supplements to be Used?

- Lists of contraindicated supplements vary by source.
  - Recipes provided for "teas," "infusions," "decoctions," and "syrups" to be used during pregnancy.
  - Information may be confusing:
    - Example: **Peppermint**
      - ▶ One source: recommended for problems with conception; headache during pregnancy; heartburn; nausea and vomiting.
      - ▶ Another source: "A uterine stimulant; avoid the oil entirely, although low doses of the dried herb can be used."
- "Peppermint is an effective remedy for nausea and vomiting but is best avoided in regular doses during pregnancy."

## Medical Literature

- **Review:** Alternative therapies for nausea and vomiting of pregnancy. Columbia University, 1998.
- **Herbal Remedies:**
  - "Herbal remedies are recommended commonly for nausea and vomiting in pregnancy, and the more common ones are available readily over the
- **Summary:**
  - "In summary, women seeking alternative, nonpharmacologic therapies for nausea and vomiting of early pregnancy have few evidence-based guidelines to assist them."

*Murphy PA. Alternative therapies for nausea and vomiting of pregnancy. Obstet Gynecol 1998;91:149-55.*

## What Do Women Assume?

- Work in progress: focus groups on use of feminine hygiene products
- Non-pregnant women
- Many appeared to read the labels for the first time
- Tacit seal of approval from the marketplace
- Women believe the government has approved these products as safe and effective because they are readily available
- "I feel like if it were really harmful, they would take it off the market."

## Conclusions

1. Lack of consistent, scientifically documented information available to:
  - women
  - health care providers
2. Women might be misled if there were pregnancy claims on dietary supplements:
  - they might assume safety based on the mere
  - fact of marketing

# Recommendations

## 1. Safety:

- Safety testing before any supplements are marketed for use during pregnancy.
- Ongoing surveillance for adverse effects of any supplements used during pregnancy.
- In the absence of accurate safety information, the health professional will not be able to give accurate advice.

# Recommendations

## 2. Warning Labels:

- Recommend warning labels on dietary supplements for which safety has not been satisfactorily demonstrated
- Could focus on safety:
  - ▶ "Use during pregnancy and nursing: the safety and effectiveness of this drug have not been proven."
- Could be similar to OTC drugs:
  - ▶ "As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product."
- Need studies of impact of labeling on habits of pregnant women

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